The Relationship Between the Political Process and the Governance of Human Embryo Research in the UK: The Case of Human Admixed (aka Hybrid) Embryos

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Abstract
This dissertation analyses the relationship between the political process and the governance framework for embryo research in the UK, with particular reference to and focus on the Human Fertilisation and Embryology Bill 2008 and the case of human admixed (aka hybrid) embryos. Two interrelated aspects are considered: the extent to which the recent political process has re-constructed the framework developed by Warnock and / or brought to the surface changes that occurred in the intervening period; and the use of the existing governance framework developed in the 1980s (The Warnock framework) as a political resource in the recent political and policy debates. A tentative evaluation of the merits of the governance framework as it emerges from the contemporary debates is suggested from the perspective of research and innovation.

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Contents

1. Introduction

The Human Fertilisation and Embryology Bill 2008 (HFE Bill 2008) allows four different kinds of human admixed embryos to be created and used in research under licence from the regulator, the Human Fertilisation and Embryology Authority (HFEA). True hybrids, resulting from the mixture of human and animal sperm and egg, are one of the four and the kind that came closest to being rejected by Parliament through amendments tabled at Commons Committee Stage. However, the kind that attracted more attention even than true hybrids, largely because it is the kind that scientists have the most interest in pursuing currently, is the kind that is formed by the transfer of a human cell nucleus or the entire contents of a human cell into an enucleated animal egg cell. This process, cell nuclear replacement, is based on the technique pioneered at Roslin in 1996 using cell nucleus and egg from the same species (in the Roslin case sheep). Human admixed embryos of this kind have been called cybrids.

Scientists are interested in creating cybrids for a number of reasons. Two featured prominently in debate: to study how embryonic stem cells can be derived from an adult cell nucleus, with the long-term aim of using embryonic stem cells as the basis for developing stem cell therapies for a wide range of diseases and traumas; and to study genetic disorders through creating embryonic stem cells from an adult cell nucleus with the relevant mutation.

Interest in pursuing research using cybrid embryos grew through 2005 and 2006 in the UK when it became clear that many of the research results based on the use of solely human material published by a team based in South Korea had been faked. Many scientists thought that cybrids were of little or no ethical significance. They were hopeful the Government would support this kind of research, under new legislation if necessary (there was some doubt as to whether it was allowed or not). Much to their dismay, at the end of 2006 the Government announced it intended to ban the creation of cybrids and some other kinds of hybrids.

This set the scene for a period of intense lobbying and debate on the question over the next eight months. At the end of this period the Government had changed its position to supporting such research under licence. This in turn set the scene for lively Parliamentary and public discussion of the issue.

In his 2008 Easter Day sermon Cardinal Keith O'Brien launched a strongly worded attack on the HFE Bill, focusing on the proposal to allow the creation of human-animal hybrid embryos for research: 'One might say that in our country we are about to have a public government endorsement of experiments of Frankenstein proportion '[1]

The Government, under pressure from within as well as without (it was rumoured that three Catholic Cabinet members were considering their positions), agreed that clauses relating to this issue and two others would not be subject to party whip when amendments were tabled in the Commons. Most members of the Government did not however abandon their support for such research. Indeed, on the Sunday before the key Commons vote, Prime Minister Gordon Brown wrote a strongly worded article in *The Observer* in support of the research. Like Cardinal O'Brien, Brown singled out hybrid embryo research as the key issue in the Bill: 'I believe that we owe it to ourselves and future generations to introduce these measures and, in particular, to give our unequivocal backing, within the right framework of rules and standards, to stem cell research.'[2]

Prime Minister Brown's enthusiasm for embryo stem cell research led critics to ask what had happened to change the Government's mind, and whether the change meant that respecting public sensibilities based on notions of the special status of the human embryo and human dignity had been abandoned.

Such questions do in part beg the scientifically and philosophically prior question of just what human admixed embryos are. The new HFE Bill has created a distinct category of human admixed embryos. For the purposes of the new Bill they are not regarded as human embryos though they will be regulated as if they are. The HFEA has interpreted the existing law so as to class cybrid embryos as human embryos and has licensed research on this basis. The distinctions are interesting in themselves. They are also important for examining the rationales for regulation.

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[1] The text of the speech is available online at: http://timescolumns.typepad.com/gledhill/2008/03/cardinal-stop-t.html (accessed 3 june 2008).

[2] 'Why I believe stem cell researchers deserve our backing', *The Observer*, 18 may 2008, available online at: http://www.guardian.co.uk/commentisfree/2008/may/18/stemcells.medicalresearch (accessed 3 june 2008).

Human embryos are in short supply and sourcing fresh human eggs in sufficient quantities to make cloned embryos is particularly difficult and not entirely risk-free for the women concerned. Accordingly, the impact of the various barriers, practical, ethical (of more than one kind), regulatory and otherwise on research using fully human material is not easy to judge. The raw materials used to create cybrids are, by contrast, in abundant supply and can be sourced without risk. Will researchers wishing to create human admixed embryos be subject to the same regulatory barriers, in practice, as those wishing to use fully human materials? Generally, what might we learn from the way regulation works in practice?

2. Literature Review and Analysis

2.1 Approach and methodological issues

The research for the dissertation is informed by a grounded theory approach, which is well suited to the subject matter under study – a process characterised by conflict and contestation leading to the construction and reconstruction of narratives and political compromises. As Strauss and Corbin put it:

> Grounded theory is an action / interaction oriented method of theory building. Whether one is studying individuals, groups, or collections, there is action / interaction, which is directed at managing, handling, carrying out, responding to a phenomenon as it exists in context or under a specific set of perceived conditions. (Strauss and Corbin, 1990, p. 104).

In these terms the phenomenon under study is the governance framework for embryo research in the context of political debate and conflict over hybrid embryos. Strauss and Corbin argue that in the grounded theory approach to study 'one does not begin with a theory, then prove it. Rather, one begins with an area of study and what is relevant to that area is allowed to emerge.' (Strauss and Corbin, 1990, p. 23). The approach to study outlined by Strauss and Corbin is reflected in part in the structure of the finished dissertation. After a discussion of the nature of the governance framework (2.2) the literature review then contains a section on the evolving debate on the governance framework in the period 2006 – 2008, with particular focus on the different actors involved and the discussion of admixed human embryos (2.3). This is followed by an analysis of the current situation (2.4). Sections 2.3 and 2.4 were used to guide semi-structured interviews with key participants in the debate. The review, analysis and interviews in turn informed sections 4 and 5, which are more thematic though still grounded in detailed description.

In his well-regarded study, *The embryo research debate: Science and the politics of reproduction*, Mulkay (1997) has chronicled the embryo research debate of the late 1980s leading up to the HFE Act 1990. His book was based on many years of study and on a substantial number of published academic papers. In the book itself he adopted a historical narrative style, presenting 'a richly descriptive account of the debate which is informed by the relevant academic literature, but which is not encumbered by constant reference to academic issues.' (Mulkay, 1997, p. x). As one would expect his approach in the book

was not out of step with that taken in the academic papers that informed it. In one such paper he explained his approach: 'I will show that this victory [for the supporters of embryo research] was accompanied by the formal definition of moral boundaries within which embryo research was required to operate; by the establishment of social mechanisms for the maintenance of these boundaries; and by an apparent transfer of ultimate control over embryo research from the scientific and medical community to Parliament.' (Mulkay, 1994, p. 197).

In this dissertation the approach adopted by Mulkay is broadly followed: thematic analysis is embedded in a description and discussion of the unfolding debate, and attention is focused on the reworking of old and establishment of new boundaries and social mechanisms of control. However, the engagement with Mulkay's study is a critical one. It seems fairly clear that Mulkay's analysis was informed by a degree of sympathy for critics of embryo research, which occasionally, to this reader, skews the analysis. The word 'apparent' might be highlighted in the above quote; control was 'apparently' transferred from scientists to politicians he says. Many practising scientists would argue strongly that there is nothing apparent about it. To give one more example: he appears to slip from arguing that a major factor in the victory of those lobbying in favour of embryo research was their promise to allow women at risk of having a child with a genetic condition the choice to avoid that, to arguing that the promise was that embryo testing could eliminate genetic disease from society (a quite different claim) (Mulkay, 1997, p. 63, p. 132). Perhaps based upon the idea that the latter claim was key he writes of 'the utopian assumptions underlying the pro-research rhetoric of hope.' (Mulkay, 1997, p. 132).

Embryo research is a controversial and contested issue. Forms of public reason that appear to or do play a role in debate need to be analysed carefully. The construction of the framework underlying the 1990 Act was strongly influenced by the Warnock Report (Warnock, 1985). But as Mulkay and other have shown in detail it was also shaped by a series of polarised debates in Parliament in the second half of the 1980s. These debates embedded and strengthened the importance of the framework outlined by Warnock in many ways, and in doing so told us something about the reasons for its success. But the process of argument and debate also highlighted conflicting aspirations that remained, sometimes half-hidden. A similar pattern of reflection by various bodies and conflict characterised the debate over the HFE Bill 2008.

One feature of the recent debate, reflecting the fact that the new Bill was an update of the old one, was the way in which the existing governance framework served as a reference point and a *political resource* during debate. Rather than debate over the merits of it, the dominant trend was to work with it and to use it. This created an impression of continuity; an impression that is in part deceptive. The extent to which changes in the content of the governance framework have occurred during these debates or perhaps come into clearer view, and the extent to which there is also continuity, is the central concern of this dissertation.

2.2 What is the nature of the governance framework as it emerges from the intense debates of the last two years?

An assessment of continuity and change in the governance framework will depend on what is considered to be the essence of the framework, and what makes an assessment of the changes difficult is that it is far from easy to pin down the essence of the framework itself. The framework has a philosophical aspect to it, but it is also quite subjective and highly political both in its foundation and in its use. It is common to find the framework criticised but also held up as an ideal. Accordingly statements made about it require interpretation.

Many critics of embryo research perceive the UK regulatory system to be one of the most 'permissive' and research friendly in the world. In principle however it is quite restrictive, irrespective of how things work in practice. The Warnock Report stated that research is a matter of public interest and concern; that unlike in fertility treatment where 'there was a fairly strong view that the freedom of the individual to take what steps he could had to be respected... in the case of research, on the other hand, there was general agreement that the issue of individual liberty did not arise.' (Warnock, 1985, p. xiv).

This underlying assumption is clearly present in the broad parameters of the governance framework. Schematically, four elements could be highlighted as defining the original framework: (i) embryos have a special status requiring protection in law and a licensing system to govern their use; (ii) research using human embryos is illegal unless permitted for specified purposes; (iii) researchers must show that it is necessary or desirable to use human embryos in each case; and (iv) some research purposes are illegal and cannot be licensed.

In Parliamentary debate Andrew Lansley MP (Shadow Secretary of State for Health) argued that research using certain kinds of hybrid embryo would breach the existing framework because insufficient attention had been given to (iii) and (iv) above; the Government had maintained (i) formally, he said, but by permitting classes of research for which no case had as yet been convincingly made and lifting most prohibitions, it had overstepped the mark.[3] Evan Harris MP (Liberal Democrat), a champion of research, disagreed. He maintained that the existing framework was intact because (i) remained unchanged and (iii) would apply to any class of embryos if and when applications were made for their use, which he saw as being the defining aspect of the framework.[4]

These observations, against a background of a schematic presentation of the nature of the Warnock framework, have some value, but to develop and situate them it is necessary to add to the picture.

Mary Warnock, architect of the framework that was substantially integrated into the 1990 Act, argued that in-vitro embryos should be accorded some respect and protection in law, but not the absolute protection we grant human life after birth. In proposing to allow research Warnock rejected the Pro-Life position. Less well known is that she also rejected the argument from potential. This is a complicated subject, not least because there are several arguments from potential and also because the arguments presented by Warnock are in her own introduction to the report rather than the report itself, leaving the question of what Committee members thought somewhat open.[5] Nevertheless, it seems fairly clear that Warnock herself argued that the embryo had to be judged on what it is rather than what it would or could become, and what is more she argued that this was the view of the majority on the committee:

> The majority of the Committee was not moved by the argument that these cells could, if certain conditions were satisfied, become human beings. They did not rely, that is to say, as the minority did, on 'potentiality', but on the consideration of what

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[3] *Commons Hansard*, 12 may 2008, columns 1073-1078.
[4] *Commons Hansard*, 12 may 2008, column 1139.
[5] As Michael Lockwood pointed out shortly after the report was published, in the body of the report we are given 'arguments for and against various positions, and we are given conclusions. But the relationship between the two often remains obscure.' See M Lockwood, 'Warnock Versus Powell (and Harridine): When Does Potential Count?', *Bioethics*, (1988), Volume 2, Number 3, p. 187.

> the embryo was at a particular time, its actual mode of existence immediately after fertilisation. (Warnock, 1985, p. xv).

This might seem clear and definitive enough. Warnock however advanced a second line of argument, or a second order argument: within society, sentiment attaches to such embryos and at a fundamental level sentiment is the basis of morality (Warnock, 1985 and 1987).[6]

This view has been criticised by a number of philosophers, notably John Harris. How is this, he asks, a *moral* argument? And how is sentiment to be judged – should we respect prejudice on this basis? (Harris, 1998). However, the key to Warnock's success was and remains that in the realm of practical politics it worked well; it facilitated and legitimated the process leading up to a vote insofar as the vote in Parliament was an expression of the sentiment of MPs and the conflicting desire to harmonise scientific advance with morality, specifically, back then, support for the family.

Clearly then, there are a number of issues in play. Reflecting on the 1980s debate, Mulkay was of the view that the Warnock Report argued for external regulation of embryo research by reference to 'the need to protect the human embryos used for experimental purposes, the need to safeguard the public interest and the need to allay widespread anxiety.' (Mulkay, 1997, p. 20). Similarly, Ruth Deech, former chair of the HFEA and now a member of the House of Lords, outlines, in the context of discussing embryo stem cell research using fully human material, several reasons that may underlie the decision to regulate and restrict embryo research: a loss of potential for development; the symbolic harm to society resulting from embryo destruction – 'if this is the way we are willing to treat the most vulnerable and helpless members of the human species, what does it say about us as moral beings?'; to appease those who feel the research is wrong; and out of respect for the effort taken to secure the material on which research is conducted. (Deech and Smajdor, 2007, pp. 195-6).

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[6] Lockwood argued that Warnock's rejection of the argument from potential was at odds with the views of the Committee expressed in the report. I disagree with this. She may have argued differently from some of the Committee, though for the reason given concerning the nature of the report this is hard to judge, but there is no contradiction as such. The key point is to distinguish between arguments based on potentiality and arguments based on the sentiments that people may hold about, among other things, the potential of the embryo.

Some writers have attempted to make a judgement about which factors appear to be most important, and changes that may have occurred over time.

Writing in 1999, the distinguished legal scholar Margaret Brazier, an opponent of embryo research, gave emphasis to the third factor highlighted by Mulkay and suggested that in reality the embryo used in research was accorded no status: 'Are embryos in reality now treated any differently from laboratory artefacts, and treated with caution only because of their tendency to generate moral panic?' (Brazier, p. 187).

Brazier feared they were treated in such a way, though she was somewhat equivocal about whether this was the case. She was aware that her side had, as she put it, 'lost the war' on the basic question of research, but didn't think it acceptable that they should have to 'simply shut up' as a consequence. Embryos as laboratory artefacts was, she argued, 'an unacceptable resolution of the debate or basis for research.' (Brazier, 1999, p. 188). Brazier was however quite clear about one thing: 'Warnock was very bothered about embryos. Who cares any more? Embryo research has flourished in the United Kingdom.' (Brazier, 1999, p. 186).

If it was a war, Martin Johnson, now Professor of Reproductive Sciences, University of Cambridge, was on the winning side. As a member of the Progress campaign in the 1980s he helped to steer the Bill through Parliament. He has been a member of the HFEA and in 2007 he was scientific advisor to the joint Parliamentary Committee (Commons and Lords) set up to scrutinise the draft Bill published by Government (hereafter called the Scrutiny Committee). In a series of papers written over the past two years, some in collaboration with Australian lawyer Kerry Petersen, he has developed the argument that today, if not in the 1980s, a distinction is made, which he would like to develop further, in regulation and practice between the embryo that is used in treatment and the embryo used in research. The latter, he believes, has little or no moral status. In other words, the issue of interest is not any inherent properties the embryo might have but what is done with it – intention is the important thing. As a supporter of research he argues that a special regulatory structure governing research is and can only be justified by a public interest in reassuring people: 'Given that, in our view, the sole continuing justifiable public interest for the present cumbersome regulatory system is the socio-political one of allaying fears, the continued existence of the HFEA as a confidence-inspiring body does seem crucial.' (Johnson and Petersen, 2008, in press).

Given its inherently political character, the Warnock framework contains the possibility of mutation and development. Taken as a whole Johnson's and Brazier's analyses in particular seem to point not simply to an evolution of the governance framework, but also to a shift in focus – away from the status of the embryo as such to other rationales for regulation and restriction of research. This analysis is reinforced by the observation that when Government, in publications, and Government Ministers, in debate, did address the specific issue of the status of the embryo in the period 2006 to the present they tended to stress the idea of setting boundaries to respect a plurality of views, in order both to support research and reflect public concerns.[7] This is not a dramatic change from the Warnock framework, which was, after all, in large part premised on respecting the sentiments present in society. But it is less focused: a plurality of views rather than a particular view regarding the status of the embryo is commonly presented as a reason to allow research with restrictions and regulations when the status of the embryo itself is considered.

One continuity between 1990 and today is the claim made by Government and the regulator that the UK system is a model for the world, facilitating world-leading research through being at the forefront of regulatory practice. Government Ministers made this point repeatedly in the Parliamentary debates and during evidence sessions to Parliamentary inquiries.[8] Ruth Deech makes a similar point, specifically about embryonic stem cell research and in general:

> From this period [2001] the UK has led the world in both advancing and monitoring stem cell research. The basis on which it does so is that established by the HFEA in 1991 for the regulation of IVF and embryo storage. (Deech and Smajdor, 2007, p. 28).

As we shall see in section 4 below, this view is not shared by some of the leading research scientists involved in the work.

2.3 Who were the key social actors and agents shaping the debate on human admixed embryos in particular? What were their motivations and priorities?

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[7] See for example Department of Health, 2006, p. v and Alan Johnson's speech introducing the Second Reading of the Bill in the Commons, 12 may 2008.
[8] As an example, see Lord Darzi's speech introducing the Second Reading of the HFE Bill in the Lords, 19 may 2007.

Parliamentarians have played an important role in recent debates, sometimes responding to pressure from scientists and campaigners for and against new developments, sometimes acting on their own initiative (relatively speaking). There was a general, if not overwhelming, sense among politicians that developments in science and a number of legal challenges to the HFE Act indicated that the time was ripe to look at the whole area of human reproduction again.

In 2002 the House of Commons Science and Technology Committee took a preliminary look and published a brief report (House of Commons Science and Technology Committee, 2002). In response the Government announced its intention to review the Act. The Committee then launched a bigger inquiry (House of Commons Science and Technology Committee, 2005a and 2005b). This helped to initiate over three years of further discussion.

Broad support for the principle of research using fully human embryos within limits and under licence was evident throughout these discussions. Indeed opponents of embryo research did not mount a challenge to it. However, over the course of the period autumn 2006 to spring 2008, human admixed embryos became one of the major issues in the public and Parliamentary debates on the HFE Bill. The issue took on a symbolic and strategic significance for all the actors involved, well beyond the importance of the work in its own terms.

The broad political and policy context in which all groups operate today is different in some key regards from the 1980s. Back then, Pro-Life views were influential in society, and were very well represented within Parliament. This constituency has less influence today, in part due to the decline in traditional conservative views. At the same time, worries about a runaway world, of science being out of control, have strengthened. When concern is expressed about embryos today it is as likely to be concern about 'slippery slopes', dignity and 'instrumentalism' as it is to be a straightforward expression of belief in the sanctity of embryonic life.

These themes are present in the academic literature as well as in popular discussion. Concern about human dignity is central to Francis Fukuyama's famous book *Our Posthuman Future* (Fukuyama, 2002). Fukuyama takes Huxley's *Brave New World* very seriously; it is not, as it is for most people, a dystopian novel not to be taken too literally, but rather a prescient analysis of one distinctly possible future. Such is the threat posed by the biotechnology revolution, argues Fukuyama, that it might change human nature and re-start history (recall

Fukuyama's even more famous book, *The End of History and the Last Man*). Fukuyama does not however oppose embryo research entirely and indeed in *Beyond Bioethics: A Proposal for Modernizing the Regulation of Human Biotechnologies* (Fukuyama and Furger, 2006) it is hybrid embryo research in particular that he thinks should be totally blocked.

The dangers of instrumentalising embryonic life is the dominant theme in Jurgen Habermas' book *The Future of Human Nature* (Habermas, 2003). Habermas' concern is that once we start instrumentalising the embryo there is no stopping (Habermas, 2003, p. 71). Today's choices have to be assessed in the light of future possibilities, and these include, he fears, a fully eugenic future, in which their parents genetically design children. This is particularly problematic, he believes, not so much because a particular genetic constitution is better than any other, but because for a person to engage with others they must feel that they are inexchangeable, and this in turn requires that their body is experienced as something natural and non-designed.

In their different ways both Fukuyama and Habermas express strong concerns about embryo research without invoking ideas based on the sanctity of embryonic human life. Roger Brownsword labels this new alignment of old and new opponents of embryo research the 'Dignitarian Alliance' (Brownsword, 2004a and 2004b). Unlike previous absolutist arguments based predominantly on Pro-Life grounds, the arguments put forward by this alliance do not clearly support outright rejection of embryo selection and research, or at least not all research.

For Pro-Life opponents of embryo research operating in this context, opposition, specifically, to hybrid embryo research expresses a number of aims and aspirations. Hybrid embryo research is something they genuinely oppose. But opposition, or at least the focus on this issue, is also both a strategic move to try to connect with an issue of particular general concern and an expression of frustration about their reduced influence and their inability to press their core concern. UK group Comment on Reproductive Ethics labels itself a secular organisation despite the affiliations of its co-founder, the well-known campaigner Josephine Quintavalle. As an individual, Quintavalle does not shy away from stating her Pro-Life views, especially when asked. But in recent debates her focus has largely been on hybrid embryos with an emphasis on scientific arguments, stressing the uselessness of the research, the claim that Government is ignoring the framework developed by Warnock in the 1980s, and the danger of pursuing research in the face of (real & perceived) public anxiety.

It is not only opponents of the research for whom hybrid embryos took on a symbolic significance. Similarly, it appears that hybrids came to symbolise a mixture of hope and frustration for advocates of the research.

For a very brief period, perhaps as little as a week in autumn 2006, some scientists tentatively expressed the hope in public that maybe hybrid embryos could be viewed as a research tool that fell outside of the Warnock framework due to the fact that they were non-viable and thus non-human under the terms of the Act (for a researcher's reflections on this, after the event, see House of Commons Science and Technology Committee, 2007b, pp. Ev70-Ev71).

The researchers interested in pursuing the work were genuinely shocked and some were quite angry when the Government proposed neither simply to allow hybrid embryo research nor to regulate it through the HFEA but instead to outlaw it. Faced with a proposed ban, they saw little option but to frame such embryos as human embryos that the HFEA might license and to launch an intense lobbying campaign.

Indeed, supporters of embryo research made this a defining issue among all those under discussion in the White Paper and later the Draft Bill, one that they were determined not to lose. Within the current Warnock framework – which requires a demonstration that embryo research is necessary or desirable – it is arguable that this led to an exaggeration of the significance of the work.[9]

Frustration about the fact that plans for a re-fashioning of the Governance framework for research and treatment more broadly in a more liberal and a more 'evidence-based' direction had been rejected by Government perhaps also played a role in focusing campaigners in favour of research on the issue of hybrids.

The Bill as it stands at the time of writing in September 2008, after the Commons Committee stage, substantially reflects the proposals that

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[9] In an interview in the *Daily Telegraph*, 12 may 2008, a week before the votes in the Commons on the relevant clauses of the Bill, fertility expert Lord Winston questioned some of the hype: 'if the hybrid embryo thing doesn't go through, it in no way shakes the body of science... It's a nice adjunct; a useful extra. But if we don't have that resource, it won't fundamentally alter the science of stem cell biology.' Available online at: http://www.telegraph.co.uk/news/1948802/Fertility-expert-Lord-Winston-'relaxed'-about-embryo-bill-failure.html (accessed 5 june 2008).

emerged in the summer of 2007 from the Scrutiny Committee, chaired by Phil Willis MP. Concretely and most notably Willis' Committee convinced the Government to support a wide range of hybrid embryo research and also to drop plans to merge the HFEA with the Human Tissue Authority. Less commented upon however is the fact that Willis, who was also chair of the Commons Science and Technology Committee at the time, effectively buried the more radical proposals that had emerged from that Committee in 2005 when it was chaired by his predecessor, Ian Gibson MP.

In its 2005 report the Science and Technology Committee set itself the task of considering, among other things, 'the balance between legislation, regulation, and reproductive freedom.' (p. 4). With the explicit or tacit support of some of those who would campaign in favour of the Bill three years later, the Committee gave a fair degree of support to the idea of 'reproductive freedom', and also, to a lesser degree, the freedom to research, when it published its findings. It argued that in the absence of evidence of harm, people should be able to pursue reproductive options and researchers should be able to pursue novel lines of inquiry. Accordingly, among other proposals it expressed sympathy for the idea of sex selection on purely social rather than medical grounds and endorsed the creation of hybrid embryos for research.

In effect, the Science and Technology Committee recommended that most conceivable research applications be allowed in principle, so long as the creations were destroyed by 14 days. Contrary to the approach taken by Government, the Science and Technology Committee proposed a slimmed-down and faster system of regulation, with a greater emphasis on trusting professionals to follow the law. Indeed, in principle the Committee suggested that the law itself could be changed so that research using embryos should be broadly permitted except for specific prohibitions (to be decided), effectively abolishing the system of regulation run by the HFEA. But, in part concerned not to endorse 'frivolous' uses of embryos, it left this somewhat open (pp. 81-82 and 148-149).

Such ambiguities hint at internal conflict on the Committee, and indeed there was plenty of that. Of particular general note is that a draft of the final report explicitly considered embracing a human rights or 'libertarian' approach to the regulation of treatment (though not research). After internal dissent this was scrapped and the Warnock framework was endorsed in the key paragraph in the published report, though without a substantial re-write of the whole document, which

was one reason given by a minority of Committee members for their decision to dissociate themselves from it.[10]

The Government was, generally speaking, unimpressed by the more radical proposals contained in the published report. In Parliamentary debate in July 2006 and in the White Paper of December 2006 it made clear that while some of the Science and Technology Committee's specific proposals might be entertained, others, such as the Committee's sympathy for social sex selection, would not be. Furthermore, the Committee's general suggestions bearing on the basis of regulation were rejected. In what might be read as a teasing comment, and certainly a significant one, the Government noted and welcomed the Committee's endorsement of the Warnock framework (Department of Health, 2006, p. 2), and took this to entail a wider agreement on the virtues of the UK system of regulation. This was an early example of the use of the Warnock framework as a *political resource* in debate. Since then everyone involved in the debate has endorsed it, whether for genuine of tactical reasons.

Overall, little argumentation was presented by Government, and perhaps any chance for a substantive discussion was lost in the furore around one specific proposal in the White Paper: the proposal to outlaw the creation of hybrid embryos for research.

The proposed ban came out of the Department of Health. One month later, signs that other parts of Government might be a little more sympathetic to the scientists' cause began to emerge. On 5 January 2007 Prime Minister Tony Blair was quoted by the BBC as saying that it might need to be looked at again: 'I'm sure that research that's really going to save lives and improve the quality of life will be able to go forward.' The HFEA, perhaps emboldened by such hints, decided at a licensing committee meeting five days later not to follow the line of the White Paper but instead to defer a decision on two applications to pursue the work pending a public inquiry it planned for the spring. By this point a lobbying campaign in favour of the work was in full swing, coordinated by Evan Harris MP. Harris was also a member of the

[10] Robert Key, a Conservative MP and a member of the Committee who supported the final report was critical of the dissenting minority and generally embarrassed about the public falling out. Minority reports were one thing he said, and not all than unusual, but in this case the minority hadn't produced one. Rather they had publicly dissociated themselves from the whole report. He suggested that after the forthcoming general election only committed, enthusiastic and dedicated members should apply to join the Committee, promising 'normal service will then be resumed to Parliament, to the public and to the scientific community.' Robert Key, Hot Flush Over HRT, *THES*, 1 april 2005.

Science and Technology Committee. In parallel with private and public lobbying he played a prominent role in the quick inquiry that the Committee organised into the issue.

The Science and Technology Committee inquiry performed a transitional role in a double sense: it started the process of pushing all branches of Government towards allowing research using the full range of hybrids; it also began the process of removing the more liberal and 'evidence-based' proposals floated in its own 2005 report from the policy agenda. In the latter sense it was transitional to the Scrutiny Committee's proposals and the approach embodied in the Bill. Contrary to the initial instincts of some of the scientists, in its report (House of Commons Science and Technology Committee 2007a) the Science and Technology Committee was very keen that hybrids should be considered human and regulated by the HFEA. Generalising from the findings of case law on fully human cloned embryos, the possibility that hybrids might fall outside the regulatory framework was highly undesirable, they argued (para. 71), despite the fact that outwith the remit of the HFEA, researchers using such entities would still be regulated by other means: there would be criminal laws prohibiting implantation of such entities into a woman, which were considered non-viable in any case. Apparently of the view that the public are a fearful if not irrational crowd liable to believe in ancient myths, the Committee argued that 'clear regulation in terms of what may and may not be permissible is necessary, for example in alleviating possible public fear that research of this nature may lead to the creation of half animal-half humans.' (para. 91).

The Scrutiny Committee picked up where the Science and Technology Committee left off on the issue of hybrids, but it had the wider remit of covering the entirety of issues covered in the draft Bill published by Government in May 2007. In terms of embryo research, it secured agreement from the Government to permit many of the concrete changes proposed by the Science and Technology Committee in 2005, but it did so through embracing at least some of the key principles of the governance framework that mark out embryo research as an area of specific concern subject to particular and at times quite burdensome regulatory principles and practices. In particular in the cause of defending hybrid embryo research and fighting off the proposed merger of the Human Tissue Authority and the HFEA the Committee and leading scientists issued ringing public endorsements of the HFEA and the merits of the Warnock framework.

The Scrutiny Committee was not the only body examining the issue around this time. As already mentioned, in parallel with the Scrutiny Committee the HFEA, now back in a driving role, led a public consultation on the issue, the most expensive consultation it has even undertaken.

A deliberative approach including a public consultation was cited as the background for the proposals in the White Paper, published in December 2006, including the proposed ban on the creation of hybrid embryos for research (Department of Health, 2006). More favourable public opinion expressed during detailed and informed consultation and deliberation (Human Fertilisation and Embryology Authority, 2007; Warburton, 2007) along with a reasoned case made by scientists is one explanation for the shift in the Government's position. It is doubtful whether the process would come close to meeting the exacting standards set for deliberation and public reason found in some of the key texts on the subjects (such as Habermas, 1990 and Rawls, 2005). However, such a comparison would probably miss the point: the public were still quite doubtful about allowing research using hybrids in the results published by the HFEA, but it was also clear that objections were not strongly held, that people could be won round through an emphasis on the medical benefits that might follow the research. The decisive factor seems to have been a change of heart at the top: there is much anecdotal and suggestive evidence that the regulator, and by this time Government, was committed to interpreting the consultation so as to allow research, if at all possible.[11]

The most significant thing about the HFEA consultation in 2007 was the framing of the debate in the light of this commitment. Analysis of the submissions to the Science and Technology Committee consultation had revealed that most people who were against hybrid embryo research and motivated enough about the issue to write in were also opposed to embryo research using fully human material (Joint Committee on the Human Tissue and Embryos (Draft) Bill (2007b), pp. 452-454). This appears to have persuaded Government that there was little to be gained in allying itself with this constituency,

[11] The latter point was given an airing on the *Today* programme, 26 april 2007. With characteristic force, Simon Jenkins stated that 'the process (consultation) is usually completely cynical.' A press release from the HFEA on the same day stated that public opinion would inform its decision but that it would not determine it; that it was important to understand public concerns to help ensure that public 'support and trust' in research was maintained. In november 2005, roughly a year before the Government proposed a ban, the authority had argued that research using hybrids should be allowed under license in its submission to the Department of Health's consultation on the Review of the HFE Act.

and to have encouraged the regulator to frame a consultation with this finding in mind, paying little attention to the views of what it now believed to be 'the usual suspects'.

That the consultation was led by the HFEA in the light of this analysis had consequences. At a public consultation meeting in London opponents of embryo research complained that many of the questions effectively marginalised their broader views on embryo research, since the principled rejection of embryo research regardless of potential benefits was not presented as an option. The Chair, Nick Ross, largely agreed, but pointed out that those scientists and others who thought human or admixed human embryos had no significant moral status, that research did not therefore need to justify itself, were also being marginalised.

The loss of the latter perspective, arising from the current framing of the debate, is often forgotten. In an interview in may 2008, Lisa Jardine, Chair of the HFEA, argued that Catholics were the only group unable to take part in the national conversation on the governance of embryo research on account of their dogmatic views.[12] This is only true to the extent that those who do not see the need for specific governance arrangements accept the terms of debate. The way in which scientists and others who make up this group relate to engagement processes is an important topic to study – how does engagement function when certain core views are not pressed?

In summary, hybrid embryos were a focus of conflict, an issue over which the broader frustrations of many of the actors involved, from widely different perspectives, were expressed, and finally one of the issues through which the framework underlying the HFE Bill 2008 was constructed, as the key players moved towards an accommodation in the first half of 2007.

2.4 Conclusion

Drawing together the discussion in sections 2.2 and 2.3 it seems reasonable to conclude that the governance framework has lost some of its previous focus on the specifics of the embryo and moved towards more general rationales for the regulation of novel technologies in sensitive areas. The legal and regulatory treatment of human admixed embryos, cybrids in particular, could be considered to have played a

[12] Available online at: http://www.guardian.co.uk/society/2008/may/28/health (accessed 5 june 2008).

role in this general shift: though they are regulated as if they are equivalent to fully human embryos, their non-viability, and the wide range of perspectives on what they are and why we should be concerned about them, broadens the class of entities subject to regulation and places greater stress on respecting a plurality of views.

Government at first leaned towards connecting with public anxieties regarding hybrid embryos, but switched tack when researchers accepted the need for regulation and applied pressure within that framework, the campaigners against the work proved to be the 'usual suspects' and the public, though still concerned, appeared more supportive when the possible medical benefits of the work were stressed.

3. Collecting the Data

Up until the end of 2005 I was, through my job, a participant in policy debates on embryo research. I continued to follow developments, attend events and conferences and occasionally write on the subject through the period of intense Parliamentary and public debate in the period 2006 up to the present. In sum this research is based, in part, on material and insights gained through a participant-observation approach.

On-the-record interviews were conducted with the people listed immediately below in summer 2008. They lasted between 45 minutes and 90 minutes each. With the exception of Calum McKellar, a phone interview, they were all conducted face-to-face.

* Dr Calum McKellar, Director of Research, Scottish Council on Human Bioethics (http://www.schb.org.uk/)
* Martin Johnson, Professor of Reproductive Sciences, University of Cambridge (http://www.pdn.cam.ac.uk/staff/johnson/index.html)
* Diane Warburton, Director, Shared Practice (www.sharedpractice.org.uk)
* Josephine Quintavalle, Founder and Director, Comment on Reproductive Ethics (http://www.corethics.org/index.php)
* Dr Murdo Macdonald, Policy Officer, Science, Religion and Technology Project, Church of Scotland (http://www.srtp.org.uk/srtpage3.shtml)
* Ian Wilmut, Chair of Reproductive Biology and Director, Scottish Centre for Regenerative Medicine, University of Edinburgh (http://www.scrm.ed.ac.uk/group_Ian_Wilmut.html)
* Austin Smith, MRC Research Professor in Stem Cell Biology and Director, Wellcome Trust Centre for Stem Cell Research, University of Cambridge (http://www.cscr.cam.ac.uk/asmith.html)
* John Burn, Professor of Clinical Genetics and Executive Director, Life Knowledge Park, Newcastle University (http://www.ncl.ac.uk/biomedicine/research/groups/profile/john.burn)

The four research scientists are all leading in their fields. They all have extensive knowledge and direct experience of working with human embryos. While their research interests are related, they are also quite distinct from each other's. This allowed me to explore the debate about admixed human embryos from different angles. All four have many years of experience of working on the issues in the political sphere.

Josephine Quintavalle and Calum McKellar are seasoned writers and campaigners. They come from different perspectives but are united by a critical perspective on developments in human reproduction and embryo research. Murdo Macdonald also has a critical perspective, perhaps similar at root to Calum McKellar's. He is however newer to this field, which, it seemed, informed a different perspective on some issues.

Diane Warburton has an expertise in public participation and in the assessment of participation processes. She did an assessment for the HFEA of the latter's 2007 public consultation on hybrids and chimeras (Warburton, 2007; Human Fertilisation and Embryology Authority, 2007).

Hammersley and Atkinson warn, on the theme of trying to get 'better' and more truthful accounts: 'this is important, but it can also be problematic: "frankness" may be as much a social accomplishment as "discretion"' (Hammersley and Atkinson, 2007, p.49). This is relevant on a number of levels for the topic under study; one issue in relation to which it seemed particular relevant was the interviews. I decided to do the interviews on-the-record because I wanted to be able to discuss the specifics of the interviewees' involvement in the events under discussion, and to use specific details in the dissertation. As such it would be impossible to effectively anonymise them, and any promise of doing so would have failed to ring true, resulting in a less rather than more open and relaxed discussion.

In addition to the eight interviews I conducted an off-the-record interview with David King, Director, Human Genetics Alert (http://www.hgalert.org). It was his preference that it be not recorded. Off the record conversations were also held with people from the regulator, the HFEA. I failed to persuade them to go on the record. In an ideal world I would have interviewed at least one MP involved in the debate and perhaps one more stem cell researcher. However, given time constraints I decided that it would be better to do this at a later stage, after the MRes was completed and the analysis had been taken a step further. I have arranged an interview with Ian Gibson MP, former chair of the House of Commons Science and Technology Committee, for mid october 2008.

In terms of substance, the interviews focused on admixed human embryos, the political process, the framework embodied in the HFE Bill and the changes and continuities between the 1980s and the contemporary debate. However, other issues were touched upon, and

indeed an interesting aspect of the interviews with the research scientists was that the interviewees raised comparisons with the political process around the Human Tissue Bill and the nature of the Human Tissue Act on several occasions. This is the comparison I plan to pursue in the PhD.

There was a general feeling that, from the researcher's point of view, the debate around tissue and the subsequent Act had gone quite badly. Martin Johnson thought that in comparison the debate on human reproduction had gone quite well. He explained the difference in part by the activities of the respective scientific communities:

> The whole business of how tissues were used by doctors to help patients never got articulated, they let the small group of patients who were very emotionally aggrieved for entirely understandable reasons make the whole case, they didn't go out and attempt to engage with them, they just hid from them, in shame almost. They shouldn't have done that. They should have gone out and said 'some of the things that have been done by our colleagues are appalling but the majority of us are not like that and this is what is driving us.' That case wasn't really made; it just wasn't made. I tore my hair out – I said to my colleagues in pathology 'why aren't you going out defending this, you're going to get clobbered if you don't; you have to go out and be prepared to take the flak'... In the UK on embryo research there wasn't a 'no go area, for the Human Tissue Act there was. You couldn't somehow appear to attack grieving parents. They didn't need to be attacked, but it could be seen as attack, and you had to accept the fact that some people would see it as attack, including some parents. People [scientists] didn't adequately engage, and they're reaping that harvest. (Interview, Johnson).

John Burn concluded the interview on a critical note about a number of regulatory structures, but he also singled out the regulation of tissue:

> One of the downsides of the British system is that they do create these most elaborate [regulatory] structures, the most dramatic of which is the Human Tissue Authority, which has grown out of that mad Dutchman in Liverpool and a misinterpretation of the Bristol inquiry. We get a knee-jerk response from a few politicians and suddenly we've got a Royal Commission and suddenly we've got a Human Tissue Authority. We're being searched; every office in the NHS was searched for body parts at the height of that nonsense. And now we've got this huge,

> elaborate employer of people who come round and inspect all our processes for handling tissue samples. They charge us thousands upon thousands of pounds for our license. If it all went away nothing would happen. It's just a process to make somebody feel better. (Interview, Burn).

An issue I plan to explore through a comparison of tissue and embryology is the question of Government thinking and action: the values it sees as important, the choices it makes (including who it chooses to listen to and why) and the structures it creates. This theme is touched on in this dissertation but will be pursued far more substantially through the comparison.

4. Analysing and Interpreting the Data

4.1 Continuity between the HFE Act 1990 & the HFE Bill 2008

There was a consensus among the interviewees that the outcome of the Parliamentary process was in broad terms predictable. For Josephine Quintavalle: 'There have been token gestures towards ethical concerns, but the ethical debate, from our perspective, was lost in 1990... The Rubicon was crossed in 1990. Since then it has been a slippery slope.' (Interview, Quintavalle). From a different perspective on some of the moral issues at stake, John Burn agrees. Burn has followed the debate for a number of years. He was on the Donaldson Committee, which in 2000 advised the Government and Parliament to amend the HFE Act 1990 to allow research on embryos aimed at understanding embryonic development and to develop embryonic stem cell therapies (at the same time as it also recommended a ban on hybrid embryo research). He is based in Newcastle and head of the Institute where some of the pioneering research has been done on cell nuclear replacement research using fully human material and also a mixture of animal and human material. He wasn't surprised about the furore, but nor was he surprised about the final outcome:

> I wasn't that surprised at the reaction we got. I was also not at all surprised that we won the Parliamentary debate. Because what happened then has happened before: it happened when we brought out the stem cell guidance ten years ago and it happened in the original Parliamentary debate. A lot of loud people make a lot of noise, and then the pragmatic largely irreligious British say 'we hear you, but we're not listening'. (Interview, Burn).

Quintavalle and Burn not only agree that the outcome was predictable; they also agree on a key reason, the medical benefit argument, using strikingly similar phrases and categories to describe the process by which opinion was shaped, though differences in moral assessment are apparent:

> You've only got to line up 200 people in wheelchairs who've been told they're going to be cured and it's a losing battle... At the event organised by Evan Harris outside Parliament [in april 2008] the BBC interviewed people in wheelchairs in favour of hybrid embryo research but not people in wheelchairs opposed. I was deeply upset to see them interviewing a young child to make the case. We need to be extremely cautious about

> promising a child that he's going to be cured of anything, when the reality is that there won't be cures in his lifetime. (Interview, Quintavalle).

> What I found dramatic about the 2001 stem cell debate, which mirrored this one exactly, was that the Lords voted 2: 1 in favour. I thought they might be more vulnerable to persuasion. When it came down to health benefits the Lords voted 2: 1 in favour. So I was never in any great doubt that it would win through on this occasion. In some ways, because I thought it would go through, I feel a greater sense of responsibility, because I think you've basically got a predictability about these debates. People who want health related things to go through can pretty well guarantee to get them through if you get somebody in a wheelchair to go on the television and their mum and dad say 'we really hope they can make a treatment'. The general power of those arguments is 2: 1 against the religious lobby. But that doesn't mean the religious lobby is always wrong. So I think we have to use that power with care, because we are to some extent in a one party state when it comes to health benefits. (Interview, Burn).

In her analysis of the HFEA public consultation on hybrids and chimeras (now all classed together as admixed human embryos in the language used in the HFE Bill 2008) Diane Warburton, while acknowledging the importance of the medical benefit argument, placed a great deal of emphasis on the power of deliberation over and above anything else. As she stressed during the interview:

> When people first think about hybrids many can't help thinking about people's heads on animal's bodies. It was the medical benefits idea that shifted it. But I think it wasn't just that, I think it was familiarity, in the deliberative process... It is the three things: the medical benefit; seeing that the scientists are reasonable people; and just having the time to think about things. With deliberation, because it engages you rationally, logic and all those sorts of thing come in, and you're talking to other people. (Interview, Warburton).

However, what is striking about the data is that there was as big a shift in opinion, in fact a *slightly* bigger one, in the opinion poll results as there was in the results from the more intense deliberative process. In the opinion polling this shift was achieved by simply changing the question to stress medical benefit: no discussion or background

material was involved. When people were asked: 'To what extent do you agree or disagree with scientists creating an embryo which contains mostly human with a small amount of animal genetic material purely for research?' 34% agreed or strongly agreed, while 48% disagreed or strongly disagreed. However, when people were asked to comment on the following statement: 'I agree with creating embryos which contain mostly human and a small amount of animal genetic material in research if it may help to understand some diseases for example Parkinson's or Motor Neurone Disease.' 61% agreed or strongly agreed and 25% disagreed or strongly disagreed.[13]

4.2 Change: the HFE Act 1990 & the HFE Bill 2008

There was also a strong consensus among the interviewees that the framework is evolving, though of course once again different moral assessments were made of this. Broadly speaking, the direction is away from an embryo centric regulatory system. It is hard to be definitive about this, for three reasons: there is a degree of opacity to the governance framework; the stated basis of the framework is today the same as it was back in the '80s, the special status of the embryo; and based on the first two points participants in the debate can choose to accentuate or play down aspects of the framework for instrumental ends.

These complexities came out in the interviews but so did a broad consensus on the overall direction of travel. For Josephine Quintavalle:

> In 1990 certain protections for the embryo were taken seriously, and there was a big battle, and the clause about embryo research having to be necessary is still a part of the law. With animal-human hybrids our view is that they are not necessary. There's a great difference between 1990 and now, and our battle should have been stronger in 1990. Certainly, the conscience of

[13] The 61% figure is, unsurprisingly, the one more commonly referred to by the HFEA. This material is taken from a HFEA Authority Paper titled 'Hybrids and Chimeras: Findings of the Consultation', Appendix F, Figure 6, authored by Helen Coath and presented to the Authority at its 5 september 2007 meeting. It was on the HFEA website for a while but is no longer there. I have been unable to locate it in any web archive so cannot reference it in a publicly accessible form. The paper is nearly identical to a public report published by the Authority (Human Fertilisation and Embryology Authority, 2007). However, in the published report the public opinion polling data is absent. It is worth noting that the gulf between the two questions is artificially wide: neither represents an accurate picture of the nature of research, one being too far to one side (blue skies research); the second too far to the other side (an instrumental conception of the nature of research).

> the nation has dulled. There hasn't been any further focus really on the rights of the embryo or the value of the human embryo, which I find extraordinary in the light of how much we know about the human embryo. The likes of John Burn at Newcastle is happy to repeat endlessly that the human embryo is just like a lump of semolina. I think he's just reinforcing the sense that I think many people in the country have about what the embryo is about, which is I think extraordinary. (Interview, Quintavalle).

Calum McKellar broadly agreed with this assessment:

> In the 1990 Act you still had the influence of the Warnock Report, which really was quite strongly in favour of this special moral status of the embryo. Whereas in the current Bill I don't think the special moral status is mentioned much at all. Basically everybody is considered as a pile of cells... In the 1990 debate, some people believed that they were piles of cells, but the debate was still around the special moral status... It is more research friendly now. There are different MPs, and people's views have changed. (Interview, McKellar).

From the other side of the fence Martin Johnson, while cautious about making the point too strongly and reflecting on the issue of whether in reality Warnock herself had adopted an embryo centric view, sees a similar process at work, an evolutionary process away from what he has called the 'tyranny of the embryo' (Johnson, 2006b). In the interview he put it like this:

> I think there is some ambiguity in the Bill because I think the Government was frightened of straying too far from Warnock. The fact that the Scrutiny Committee and in fact the Department [of Health] really and people in Parliament have said effectively that Warnock still provided the moral basis for how we treat the embryo is questionable. Mary Warnock herself when we interviewed her more or less agreed with that, she said it wasn't really about the moral status of the embryo, that was the one thing they could never agree on, what they could agree on more was on how you treat the embryo. It was a very practical utilitarian approach. So to that extent I think the current Bill does embody the Warnock principle, but not at the level of ethics in the strict sense of the word... I think that the current Bill, in bringing in the concept of the permitted embryo goes a long way along the route I'm talking about. (Interview, Johnson).

Critics of embryo research see the process of moving away from the 'tyranny of the embryo' in the substance if not the form of regulation as equating to a more research friendly environment. In one sense they are clearly right, as Burn acknowledges. But one striking feature of the interviews and some of the debates in the various Parliamentary Committees is just how frustrated some research scientists are with what they perceive to be the failures of the political process, the burdens of regulation and its irrational features.

In sections 4.3-4.6 immediately below the hybrids story is retold through the words of some of the scientists closely involved in the process. This adds to and slightly modifies the analysis of section 2.3 above, placing the emphasis at least as much on concrete concerns linked to the frustrations of practical activity as aspirations deliberately to modify the governance framework in the political sphere. This in turn lays the basis for an assessment of scientists' approach to regulation in this area in 4.7.

4.3 The beginning or the end of the road for hybrid embryo research?

In the autumn of 2007, Pro-Life campaigners felt they had been handed a remarkably powerful propaganda coup. Ian Wilmut, 'father' of Dolly the cloned sheep and an internationally renowned pioneer of cell nuclear replacement as a research tool for studying human diseases, announced he was abandoning the field to pursue what he regarded as a superior approach. He had decided to devote all his energy to studying the promising approach of induced Pluripotent Stem Cells (iPSC), a technique pioneered by Shinya Yamanaka in which cells apparently equivalent to embryonic stem cells are produced directly from an adult cell nucleus without the creation of an embryo. Press commentary suggesting that this might be because Wilmut thought it ethically superior as well as scientifically superior was the icing on the cake for the critics of hybrid embryo research.

In reality, Wilmut is crystal clear that his shift in focus was not based on ethics, and he continues to support all avenues of research:

> There is no ethical aspect to this. That's easy [to answer]. It was a matter of focus. It seemed to me that this was the most likely way of achieving our goal, which has proved to be true. But I think that human nuclear transfer should continue along with other, non-human primate nuclear transfer, to develop the technique, because it is never easy to tell how a technique will be used. (Interview, Wilmut).

The real story is Wilmut's and others' struggle to make cloning work, caused in part by the burdensome and slow moving nature of the UK political and regulatory system. There are other complications as there often are in science: scientific competition is involved and, as Wilmut freely admits, he was also struggling to cope with an industrial tribunal case and new administrative responsibilities. As he said: 'it's a tale of human frailty, and of the complications of research really.' (Wilmut, Interview).

In the outline that follows the story is necessarily heavily abbreviated. First of all, I consider the competitive aspect, which is influenced by an assessment of scientific possibilities and the practicalities of what particular teams can hope to achieve.

Wilmut's view is that while there are still worthwhile experiments to perform in cloning, it is likely to be judged as a footnote in the history of research into embryonic stem cells. Austin Smith, a leading UK embryonic stem cell researcher, who, unlike Wilmut, has never been a great enthusiast for the merits of cell nuclear replacement research, shares this view:

> Yamanaka's work is the way forward, almost certainly. It's clearly where all the major effort will go. Now, it's always possible in science that some roadblock will come up that people haven't envisaged. So you never put all your eggs in one basket. It is also possible that things could be learnt from cybrid embryos. But it's not obvious why you'd necessarily have to use human donor cells; though there could be arguments for it. iPS cell technology doesn't mean scientists shouldn't do nuclear transfer. It just means that we've moved from a position where that was the only foreseeable route and everyone knew it was deeply unsatisfactory to a position where we can now see a much simpler and cleaner route. So it's just obvious where you put most of your money. (Interview, Smith).

John Burn at Newcastle doesn't necessarily disagree with the point about the footnote, but he thinks all research tools might turn out to be footnotes. This is where scientific competition enters the story:

> Induced pluripotency is a good example of eleven year olds playing football. One in goal and ten chase the ball. As soon as iPSC came along it was 'let's all rush over there' before they'd had a chance to look at the outcome... The problem with the

> induced pluripotency is that there is a bunch of people in America in particular who couldn't do hybrid work or human egg work so they're bound to say 'this is the greatest thing since sliced bread'. The same thing applies to Edinburgh. Edinburgh were not well placed to pursue the human embryonic route, so inevitably Ian Wilmut's going to say 'we'll try this one' because it plays to their strengths. The embryonic one plays to our strengths. So we're going to major on that because it gives us an edge when it comes to competing for research funds. But that's not to exclude everything else. (Interview, Burn).

What Wilmut and Burn agree about is that the best argument for pursuing hybrid embryo research is to compare and contrast hybrids with fully human material, or with material from the same species. Burn believes Newcastle scientists are set up well to do that. Wilmut on the other hand believes that the time when hybrids embryos were most relevant from this point of view was around 2004 or 2005:

> To me the significance of the hybrid embryos, if we call them that, is probably about three or four years ago... There was a time when the cells produced in Shanghai by Professor Sheng and her colleagues were the only cells which were approaching being equivalent to embryo stem cells that had been produced with a human nucleus, and they were produced by putting human nuclei into rabbit oocytes. So it seemed important to follow that up. The second reason for doing it was that if you contrasted what happened during the first 24 hours if you put a human nucleus into a rabbit oocyte and a rabbit into a rabbit you might learn something about the differences between the species which were at that time believed to be unknown but causing the failure of primate nuclear transfer. So at that time it seemed a very appropriate thing to think of doing, and for that reason it may still be appropriate in order to learn about the cloning process but I don't see nuclear transfer in this way as having a big impact any more.' (Interview, Wilmut).

It was his attempts to do the comparison at the time that brought Wilmut up against practical barriers, as Burn suggests, but also regulatory and political ones. Wilmut makes the following observation, linking his views on the time period in which the work was most relevant to his views on the political process:

> The political system was slow to deal with this in this country, so that by the time that Parliament was debating it we already

> knew from work in Boston that the procedure [admixed cnr] was not going to produce embryo stem cell lines very efficiently if at all. The thing which was critical to do was to try to repeat Sheng's work and to see if it could be improved. The evidence so far is that it's difficult to repeat and there's no evidence of improvement. But at that point, in the absence of Yamanaka's work, it was an important thing to follow. (Interview, Wilmut).

When he tried to investigate fully human cloned embryos and hybrids in parallel first one leg of the procedure was hit, then the other.

He had invested a lot of energy in developing a collaboration with the South Korean scientist Hwang, who appeared to be doing better work in human cloning research than anyone else. When it was discovered, in 2005, that many of the results had been faked, it was quite a body blow to Wilmut for a whole number of reasons. Not the least of these was that he had already spent four years negotiating the regulatory and scientific hurdles in an attempt to get to the point where he could start to work on cloning using fully human material. But he picked himself up, and began discussions with colleagues locally about securing a supply of fresh human eggs, only for the other leg of the process to be hit:

> I went across to the clinic one morning, I thought I'd got animal oocyctes in the bag at that point, we were likely to get permission... We came up with an algorithm [for the procurement of human oocytes] that said roughly that the first six oocytes would go to the couple, and then progressively as it went on past that we would get more. That conversation was 11 o'clock one day. At one o'clock that day I got a phone call from someone in the HFEA to inform me that the Government had just announced that it was minded to ban the use of animal oocytes... it was probably November 2006. I thought 'oh bugger this' and sort of lost patience and kept on doing other things. (Interview, Wilmut).

One year later his interest ended altogether.

4.4 Hybrids and the political process: the resolution in 2007

Smith picks up the story of what happened when the Government announced that it planned to ban work using hybrid embryos late in 2006:

> The Government White Paper saying they would ban this area was just gob-smacking... If you talk to the public, and ask, is it better to put a woman through hormonal stimulation to get human eggs or should you go down to the abattoir and get cow eggs? It's a no brainer. So why do we get so exercised? It's just a very, very bizarre place to be in I think. (Interview, Smith)

In response to this, says Smith, scientists had to make a number of pragmatic decisions. One was to work within the framework of UK law, though he demurs at the suggestion that this entailed expressing strong support for the HFEA:

> You're faced with the reality of UK law, that the way to deal with that situation is to get these things recognised as human embryos so they can be licensed for research. If you don't do that, there's a problem... From the point of view of the scientists you just want to do the bloody experiment. When these kinds of situations arise, and you suddenly find there's some political threat, some regulatory threat, then all you're interested in is finding your way round that... the key thing was to have these entities recognised as human embryos and therefore covered by the Act, and unfortunately that means we have to take the HFEA as well! So it was a marriage of convenience I suppose. I guess that may also be why any criticism of the HFEA was rather muted, because the key point was to have these entities recognised under the Act, and therefore it would be difficult to argue at the same time that we should get rid of the HFEA, although I still think logically that you could have argued that, but apparently not to politicians. (Interview, Smith).

Smith also makes a distinction, to explain who was defending what during the discussions in the first half of 2007:

> For me it [hybrid embryo research] was symbolically important to protect but not practically. Many of the other scientists started off from the position that this was practically important to protect. This was a rapidly changing time in science. The implications of Yamanaka, people just hadn't realised. (Interview, Smith).

Yamanaka's work is mentioned only very briefly in the hearings. Developing the point about defending the principle as opposed to defending the actual research, in Smith's view there was a reason for

4.6 Simply the best?

Scientists disagree and will continue to disagree on the most promising avenues of scientific research, but they clearly agreed on the necessity to defend the principle of research. Given the problems they had experienced it is no surprise that a number of scientists also reject the claim made by Government and the regulator that the UK leads the world in regulation and research.

During the Scrutiny Committee discussions, Committee member (Lord) Professor Winston was a lone voice challenging the Government view: 'America has an unregulated scientific community and yet it is producing by far the most effective and most published and most respected papers in stem cell biology in the world, even though of course it has a President who is set against it.' (Joint Committee on the Human Tissue and Embryos (Draft) Bill (2007b), p. 66).

However, others concur with his assessment on the relationship between the UK system and innovation. Austin Smith is very forthright:

> I can't see any credible basis for claiming that the UK is in any kind of leading position in human embryo research in terms of the science... in practical terms it's not easy to do in the UK, and we've lost out because of that actually compared with other countries... It's not even just the private sector in the US, it's just non-NIH funded, so there's Howard Hughes and JDRF and many others. There are other European countries like Belgium and Sweden where they have good quality IVF clinics with a reasonable level of research going on. In the UK it really hasn't happened. That may be to do with broader issues than the regulatory framework. It may be to do with the way that IVF is funded in this country and the separation of clinical treatment from research, which is an issue throughout the NHS. But the idea of the HFEA having a role in the UK supposedly leading the world in stem cell research is farcical... the HFEA reasonably enough wants to bang its own drum and politicians like to have something to bang their drum about. They still seem to be obsessed by the idea that somehow we're ahead of the US because of the Federal ban on funding. Any idiot could just look at the amount of funding from other sources going into this area in the US, the number of researchers, any metric you want to use – it's clear. (Interview, Smith).

the low profile given to Yamanaka's work beyond the fact that his work using human cells had not been published at the time:

> The context of the hearings was to defend this area of research [hybrids] so you didn't actually want to say at this point, well, you know, here's a new technology that is the way forward so we don't need this any more because, you know, you'd be shooting yourself in the foot. (Interview, Smith).

4.5 The mediating role of the AMS and the Scrutiny Committee

It was not just that scientists rebelled against the idea of banning research and wanted to fight for the principle that research that carried no risk of harm should be allowed. Instinctively scientists were also unhappy because they felt that complete ignorance of biology was leading to an attempt to impose rigid notions, rigid categories on complex biological phenomena. Professor Martin Bobrow put it succinctly, and a little tactfully, during an evidence session to inform the Science and Technology Committee's inquiry on the subject:

> There is a huge gradation of everything from a single gene in an otherwise completely mouse cell to the reciprocal, and somewhere along there we have to draw a line. The definitions of humanity that I know about all apply to things that walk upon the earth rather than things that live on the bottom of the Petrie dish and I am not sure that there is a straightforward answer [to the question of whether hybrids are human or not]. (House of Commons Science and Technology Committee (2007b), p. Ev 38).

A counter discourse to the political view that hybrids are a distinct category requiring clear definition and sensitive treatment became somewhat public in this way and in particular through the Academy of Medical Science's publication *Inter-species embryos* (The Academy of Medical Sciences, 2007) produced by a Committee chaired by Bobrow. This was wrapped up with scientists' desire to carve out a publicly recognised space for their expertise and autonomy. The convergence of the two strands, the mediation of them, was through the Scrutiny Committee's idea that discretion should be given to the regulator to work with scientists in licensing novel applications, and that in principle most conceivable forms of human or admixed human embryo should be able to be created for research purposes. Further public and Parliamentary controversy was to follow, but at the level of political deal making this resolved the issue.

4.7 Scientists and regulation

What does this recent history of conflict over hybrid embryo research tell us about scientists' attitudes towards regulation in this area? As Mulkay tells the story, in the 1980s, a number of individual scientists, many eminent in the field, as well as some scientific institutions and journals at an editorial level, opposed the framework outlined by Warnock. Robert Edwards, IVF pioneer, responded in this way: 'I deny the argument that [the] scientific impetus will necessarily lead to silly experiments. It would be unwise to jeopardise future advances by short-term recourse to the criminal law.' Another prominent researcher thought that 'the first part of the report is practical and sensible because it was based on at least 10 years of experience [with IVF]. When you come to the regulation of research it draws on science fiction and so is tinged with hysteria.' (Mulkay, 1997, p. 21).

But, continues Mulkay, when they saw the way the political wind was blowing they fell in behind Warnock in the hope and expectation that regulation of research would provide some political protection for their work. As one MP put it: 'the Medical Research Council recanted and threw its full weight behind Warnock.' (Mulkay, 1997, p. 27).

Mulkay's discussion of the process gives the impression of a *volte-face*, and implies a compliment about scientists' tactical sense. But if it is a compliment, it is one that Johnson suspects may be a back-handed one. Johnson, an active participant in the debates of the 1980s, resists the idea that it was primarily an instrumental move by scientists. Yes, scientists did scheme, he argues, but substantially what they did was to throw the decision open to society and lay out the options – out of this they expected regulations to emerge:

> I don't think we tried to push the research argument, we just pointed out what had happened as a result of research and the consequences of banning further research. I don't think we were dishonest at all in that. (Interview, Johnson).

Indeed, going further back in time, this is how Johnson believes Edwards approached the issue in the 1970s, and how he believes most scientists approach the issue today:

> He didn't resist regulation, you don't see him out there resisting regulation, he wanted to have the debate in society, he was trying to get society to discuss this rationally for years before it

> did, until Louise Brown was born, and then it [society] did because it could suddenly see there was something to discuss and so on... the majority of scientists and doctors are perfectly happy to be regulated as long as it's done reasonably, and they can see that there is a genuine public concern. I think apart from the odd one or two they are broadly of the view that as long as regulation is done intelligently and in an informed way with widespread debate, then it's perfectly fine. You may kick against it, you may get irritated by it and you may criticise it, but all of that is legitimate, because it is never going to be perfect and you have to be articulating your concerns.' (Interview, Johnson).

Perhaps not surprisingly, former chair of the HFEA Ruth Deech is more sympathetic to Mulkay's (implied) argument. In what reads like a direct rejoinder to Johnson she argues that in a key paper Johnson refers to (Edwards and Sharpe, 1971) 'Edwards was perhaps committed to the facilitation of science rather than to the imposition of restraints based on public concerns.' (Deech and Smajdor, 2007, p. 29). She develops this point, generalising to broader medical and scientific opinion:

> His [Edwards'] ambivalent attitude towards regulation was revealed when he later described state interference in reproductive medicine as 'Nazism and Stalinism'. If nothing else, this illustrates the way scientific and medical support for regulation fluctuates in relation to what the scientists may regard as the imperative for freedom in research. (Deech and Smajdor, 2007, p. 29).

This discussion and dispute between Mulkay, Johnson and Deech tells us something interesting and useful about the approach of scientists to the regulatory process and the governance framework, in addition to their concerns and frustrations.

Johnson's approach is that it is reasonable and fair to push the boundaries of public opinion: one should operate at that point, neither behind it nor too far ahead of it. In his view the Department of Health was behind it and the Scrutiny Committee in the right place in the struggle to frame the new Bill. By implication the Science and Technology Committee was too far ahead of it in its 2005 report.

Exactly who was pursuing what, when and why are matters of judgement. Issues of temperament and views on the way the political process should work are clearly crucial. The history of the hybrids

debate suggests that for that community of scientists in the first half of 2007 the instrumental approach to regulation was clearly present. Furthermore, while Johnson speaks of it being reasonable to kick against the framework others seem to speak more strongly.

However, scientists aren't instinctive political radicals any more than anyone else. A distinction needs to be made between their personal views, the views they express in public even, and the extent to which they are inclined or willing to really pursue such ideas in the political sphere. In large part the main concern of many, in Smith's words, is to 'do the bloody experiment'. Johnson's view is too rosy and reasonable sounding, but he is right to say that scientists rarely reject regulation as a mater of principle. Rather, more typically, they resent the implied criticism involved in the idea of specific regulation while also holding out the hope for an idealised, smooth and efficient system of regulation, rather than rejecting regulation as such.

4.8 The political process and regulation: all eyes on the HFEA?

The tendency to use the governance framework as a resource rather than to debate its merits in the political realm has ultimately reinforced a pattern of continuity in regulatory structures. Connected to this the strong sentiment that the outcome of the Parliamentary process was predictable led all the parties to focus a significant degree of attention on the regulatory process throughout the period of debate in the political sphere.

For the critics of embryo research, because they felt and feel that their ability to influence political decision-making is limited, in many ways the long game was always to focus on regulation. For example, Quintavalle, through Court cases, campaigning activity and dialogue if she can get it is seeking to use the notion that embryo research must be considered 'necessary' in order to limit research applications.

On the other side Evan Harris MP has led a campaigning machine during the Parliamentary debates on the Bill, one that has won the admiration of Josephine Quintavalle and teasing comments from Government Ministers, who suggested he was developing an alternative career as a Parliamentary draftsman. However, notwithstanding Quintavalle's observation, Harris has also bowed to political realities and retreated from the more radical proposals contained in the report of the House of Commons Science and Technology published in 2005 that he championed. In Parliamentary debate in 2008 he suggested that if no one was happy with the

framework for embryo research it must be right, a comment meant somewhat ironically no doubt, but an interesting one nonetheless.[14]

In summary, once liberal critics such as Harris along with scientists had come to the conclusion that they would not be able explicitly to shake up the process of regulation, they adopted a similar approach to that of Josephine Quintavalle and settled down to work with the regulator.

[14] *Commons Hansard*, 19 may 2008, column 53.

5. Findings

That the existing framework was used as a resource in the debate over hybrids rather than being discussed on its merits led to or reinforced a trend towards a diminution in the specificity of governance arrangements in this area. At no point was there a real or substantive argument or discussion of the merits of embryo research using fully human material. This process of normalisation was further strengthened by the fact that the debate that did occur, the debate in which embryos were to some degree considered, was over hybrid embryos, embryos that are not viable in most cases. The issues considered in this context were more to do with human dignity and slippery slopes on the one side, and medical benefits on the other. Human embryos were swept up in this debate through the process of either considering hybrid embryos to be explicitly human (the HFEA's approach) or else deserving of identical or near identical regulation (the approach in the HFE Bill 2008).

The Government transferred the issue further away from the nature of the entities being regulated, and at the same time neutered any substantive debate, by stressing that a primary rationale for regulation and restriction was to create a space for and to respect a plurality of views.

Scientists are escaping 'the tyranny of the embryo' through a slow evolutionary process, but this is perhaps cold comfort for at least some research scientists. The flip side of the lack of a principled debate is that 'freedom to research' was not pressed either. One consequence of this is that while critics argue that researchers can 'get away with anything', researchers are in fact far from happy. They had to fight over something they hoped they wouldn't have needed to. When the dust settled, what had they got? Regulatory restrictions based on respecting a plurality of views may be no less onerous than those based on respecting the embryo, while the specific restrictions on hybrids seem perverse to practising scientists. How the regulation of admixed human embryo research will develop in practice remains an open question. John Burn suggests that 'had it been any other scientific procedure it [the regulation] would have slackened off a bit, but I think it will get the full fury of bureaucratic regulation, potentially more so [than fully human material].' (Interview, Burn).

If that turns out to be the case scientists will reflect that regulations on this issue at least are particularly burdensome and irrational. What seems fairly clear is that at the moment at least, scientists at the

coalface do not support claims by the Government and the regulator that the UK is the best of all possible places to do embryo research. Its virtue is said to be that the UK system contains tensions, but are some of those tensions imagined? If there were greater 'freedom to research' would it really bring the public-opinion house down?

The political messages sent from Parliament are very important, as are detailed changes proposed to regulation contained in the Bill, but in contemporary practice this reinforces the fact that the HFEA is the only game in town. For this reason, despite their criticisms of the regulatory framework and the regulator most participants in the debate either need or want to work with it. The inability or unwillingness of the parties to challenge the framework is its ultimate source of strength. This allows Government and the regulator a degree of choice in the values it promotes and the decisions it takes.

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